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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/687,122	10/13/2000	Alessandra Boe	P/717-181(CONT)	6984

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EXAMINER	
MURPHY, JOSEPH F	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 01/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/687,122	BOE ET AL.	
	Examiner	Art Unit	
	Joseph F Murphy	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11/9/2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-32* is/are pending in the application.

4a) Of the above claim(s) *22-24 and 32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21, 25-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Formal Matters

Claims 21-32 are pending. Claims 22-24, 32 stand withdrawn from consideration pursuant to 37 CFR 1.142(b). Claims 21, 25-31 are under consideration.

Response to Arguments

Applicant's arguments filed 11-09/2004 have been fully considered but they are not persuasive for the reason set forth below. In addition, new issues are also set forth below.

Claim Rejections - 35 USC § 112 first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21, 25-31 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification as originally filed does not provide support for the invention as now claimed: A method for treating autoimmune and inflammatory diseases "against which a TNF receptor is effective".

Applicant's amendment, filed 6/8/2004 does not provide sufficient direction for the written description for the above mentioned limitation of claim 21. The specification as filed does not provide a written description or set forth the metes and bounds of this phrase. The specification does not provide direction for the instant sequence encompassing the above-mentioned "limitations" as they are currently recited. The instant claims now recite limitations

which were not clearly disclosed in the specification as-filed, and now change the scope of the instant disclosure as-filed. Such limitations recited in the present claims, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

Applicant is required to cancel the new matter in the response to this Office action

Alternatively, applicant is invited to provide sufficient written support for the "limitations" indicated above.

Claims 21, 25-29 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating septic shock by administration of a TNF receptor, or TBP-1 in combination with DHEA, does not reasonably provide enablement for a method of treating autoimmune and inflammatory diseases by administration of a TNF receptor, or TBP-1 in combination with DHEA, for reasons of record set forth in the Office Action of Paper No. 13, 5/5/2003, 11/25/2003 and 8/9/2004. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The rejection of record set forth that claim 21 is directed to a method of treatment of autoimmune and inflammatory disease in a patient by administration of DHEA in combination with a TNF receptor, while claims 25-29 are directed to methods of treatment of autoimmune and inflammatory diseases in a patient by administration of DHEA in combination with TBP-1. Thus, the claim encompasses the treatment of any and all inflammatory and autoimmune diseases by administration of a TNF receptor, including TBP-1, in combination with DHEA. Applicant has amended the claims to change claim 21 into the Jepson format with the known process in the preamble and the improvement in the body of the claim.

Applicant argues that the examiner is incorrect in stating that the claims are directed to the treatment of "any and all inflammatory and autoimmune diseases". The words "against which a tumor necrosis does limit and further define under the claim". The words "against which a tumor necrosis factor (TNF) receptor effective" cannot be read out of the claim as the examiner is apparently doing. The claim is only directed to a method for treating those autoimmune and inflammatory diseases against which TNF receptor effective in a patient. Applicant further argues, and present several abstracts, that there is a large number of inflammatory and autoimmune diseases, against which it is known that a tumor necrosis factor receptor is effective, and that this should be sufficient to establish enablement for the entire genus.
However, as set forth supra, the limitation "against which a tumor necrosis factor (TNF) receptor effective" is new matter, and the specification as filed does not provide a written description or set forth the metes and bounds of this phrase. Thus, the claims are being interpreted to encompass the treatment of any and all inflammatory and autoimmune diseases by administration of a TNF receptor, including TBP-1, in combination with DHEA, wile the

Specification demonstrates the effectiveness of the claimed treatment in a septic shock model, and the art teaches the effectiveness of TNF receptor alone in RA, SLE and the NOD mouse model of diabetes, this is not demonstrative of any and all autoimmune and inflammatory conditions, and does not enable one of skill in the art to treat any and all autoimmune and inflammatory conditions using the claimed method. No nexus haprovided between the treatment of RA, SLE, the NOD mouse model of diabetes, or septic shock and any and all other inflammatory and autoimmune diseases. Applicant is required to enable one of skill in the art to make and use the claimed invention, while the claims encompass methods for which the skilled artisan would need to carry out experimentation to determine the effectiveness of the claimed treatment method in any and all other autoimmune and inflammatory conditions. Since the nexus between the treatment of RA, SLE, the NOD mouse model of diabetes or septic shock, and the treatment of any and all autoimmune and inflammatory diseases is not set forth in the Specification, or recognized in the art, this experimentation would be undue since no teachings are provided that would allow one of skill in the art to predict that the claimed method would be efficacious in treating any and all other autoimmune and inflammatory diseases.

Claim Rejections - 35 USC § 112 second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 21, 25-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 21 is vague and indefinite in that the method recites that the TNF receptor is administered "in combination" with DHEA, then recites that they are administered "separately". In reviewing a claim for compliance with 35 U.S.C. 112, second paragraph, the examiner must consider the claim as a whole to determine whether the claim apprises one of ordinary skill in the art of its scope and, therefore, serves the notice function required by 35 U.S.C. 112, second paragraph "by providing clear warning to others as to what constitutes infringement of the patent". See, e.g., Solomon v. Kimberly-Clark Corp., 216 F.3d 1372, 1379, 55 USPQ2d 1279, 1283 (Fed. Cir. 2000). MPEP 2173.02, MPEP 2173.02. In the instant case, the contradictory steps of the claimed method would not indicate to the skilled artisan of the metes and bounds of the claim. Claims 25-31 are rejected insofar as they depend on the contradictory steps of claim 21.

Conclusion

Claims 21, 25-31 are rejected.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Murphy whose telephone number is (571) 272-0877. The examiner can normally be reached Monday through Friday from 7:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961.

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Joseph F. Murphy, Ph. D.
Patent Examiner
Art Unit 1646
January 21, 2005